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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/705,195

11/10/2003

Volker Buttcher

0147-0253p

5787

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7590

10/19/2006

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EXAMINER

PAGE, BRENT T

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/705,195

Applicant(s)

BUTTCHER ET AL.

Examiner

Brent Page

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 6-9, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 10-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09807063.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/10/2003</u> | 6) <input checked="" type="checkbox"/> Other: <u>IDS, 02/23/2004</u>                    |

### **DETAILED ACTION**

Applicant's election without traverse of Group I in the reply filed on 08/02/2006 is acknowledged.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is drawn to a nucleic acid from a bacterium. The claim is therefore drawn to the nucleic acid in any state including that of its original state. Accordingly, the claim is drawn to a product of nature, which is non-statutory subject matter.

See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. V. Kalo inoculant Co.*, 233 U.S. 127 (1948), and *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931).

This rejection can be overcome by amendment of claim 1 to indicate that the nucleic acid has been isolated. New Matter should be avoided.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 10-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a vector, a host cell, a transgenic plant, a method of making a transgenic plant and a method for producing a branching enzyme, all of which comprise any nucleic acid molecule encoding any branching enzyme from a bacterium of the genus *Neisseria*, wherein the nucleic acid deviates due to degeneracy of the code from the sequence of a nucleic acid that "hybridizes" to a nucleic acid that encodes any protein that has a sequence wherein the first 100 amino acids have a homology of at least 65% to SEQ ID NO: 2. The term "hybridizes" is interpreted to read on any length of sequence capable of hybridizing under any conditions to said sequences. The claims therefore encompass multitudes of sequences from multiple species that encode any branching enzyme.

In contrast, the specification only provides guidance for a full length branching enzyme from the *Neisseria denitrificans* species defined by SEQ ID NO 1. The specification does not provide guidance for any other nucleic acid sequences encoding a branching enzyme from a *Neisseria* species.

The function of starch branching enzymes is unpredictable. In a review of the regulation of starch metabolism in plants Tetlow et al (2004 *Journal of Experimental Botany* 55(406):2131-2145) disclose that only a few genetic variations that lead to

Art Unit: 1638

known phenotypes are even known for starch branching enzymes as evidenced by the statement "To date, only mutations in SBEII isoforms give clear phenotypes, and in monocots this is confined to SBEIIb mutants" (see page 2134 second column, last paragraph). Tetlow et al disclose a mutant of SBEIIa that displayed a clear phenotype in leaf starch but showed no alterations in the storage starch of the endosperm (See page 2134 Column 2, last paragraph, for example). Tetlow et al further disclose that other genes are capable of affecting the expression of at least SBEIIb, but not all of these genes are known (see page 2135, 1<sup>st</sup> column, 3<sup>rd</sup> paragraph, for example). Without clear guidance as to a minimal sequence required for branching enzyme function, it would be undue experimentation for one of skill in the art to evaluate the claimed multitudes of sequences for their ability to encode branching enzymes.

Given the state of the art, the disclosure by Tetlow et al and the unpredictability as disclosed above, it would be undue experimentation for one of skill in the art to isolate and evaluate all Neisseria nucleic acids that encode branching enzymes as broadly claimed.

Claims 1-5 and 10-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a vector, a host cell, a transgenic plant, a method of making a transgenic plant and a method for producing a branching enzyme,

Art Unit: 1638

all of which comprise any nucleic acid molecule encoding any branching enzyme from a bacterium of the genus *Neisseria*, wherein the nucleic acid deviates due to degeneracy of the code from the sequence of a nucleic acid that "hybridizes" to a nucleic acid that encodes any protein that has a sequence wherein the first 100 amino acids have a homology of at least 65% to SEQ ID NO: 2. The term "hybridizes" is interpreted to read on any length of sequence capable of hybridizing under any conditions to said sequences. The claims therefore encompass multitudes of sequences from multiple species that encode any branching enzyme.

In contrast, the specification only provides guidance for a full length branching enzyme from the *Neisseria denitrificans* species defined by SEQ ID NO 1. The specification does not provide guidance for any other nucleic acid sequences encoding a branching enzyme from a *Neisseria* species.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed

Art Unit: 1638

genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence). In the present case, the structure that is required for the claimed functional activity has not been described.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described.

Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 in parts a-g recite "nucleic acid molecules". It is unclear whether applicant is intending to encompass multiple embodiments given that the first line of the claim recites "a nucleic acid molecule" and that parts a and b in particular define the "nucleic acid molecules" by a single SEQ ID NO. If Applicant intends for the selection of a single nucleic acid from the claimed group, appropriate changes should be made. New Matter should be avoided.

Claims 1-5 and 10-14 are free of the prior art given the failure of the prior art to teach or reasonably suggest a nucleic acid molecule encoding a branching enzyme from a bacterium of the Neisseria genus, or a vector, host cell and method for producing a branching enzyme comprising said nucleic acid sequence, or a transgenic plant comprising said nucleic acid sequence linked to a signal sequence for localization of the encoded protein to the plastids of the cells.

No claims are allowed.

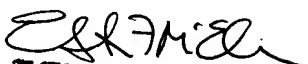


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (514)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

  
ELIZABETH MCELWAIN  
PRIMARY EXAMINER